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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,392	11/28/2000	Karen Moore	MPI97-018CP1DV1M	9536

7590 10/21/2003

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EXAMINER	
MURPHY, JOSEPH F	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/724,392	MOORE ET AL.	
	Examiner	Art Unit	
	Joseph F Murphy	1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 July 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ they raise the issue of new matter (see Note below);
   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____.
3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *32-46*.

   Claim(s) withdrawn from consideration: _____.
8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because: The amendment and arguments have been fully considered but are not persuasive. The claims were rejected under 35 USC 101 and 112 first paragraph because while the instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby, it does not disclose the biological role of this protein or its significance; therefore the claimed method of identifying a compound is not supported by either a credible, specific and substantial asserted utility or a well-established utility. Applicant argues that the utility of diagnostics and screening assays for identification are well established, and that the assertion of utility is based upon the expression pattern as set forth in Example 9 of the specification. However, the fact that the claimed invention is a method of identifying a compound which modulates a GPCR is no sufficient to establish a specific and substantial utility because there is no specific use of that modulation provided. Applicant argues that the method is useful in diagnosing and treating diseases, but there is no nexus provided by the instant specification to support this use. Additionally, Example 9 of the Specification demonstrates that the polynucleotide is expressed in various sections of the brain, this asserted utility is not specific or substantial because there is no comparison to the expression in other tissues, where the polynucleotide could serve as a tissue marker, and there is no correlation between the expression of the I5E polynucleotide and any function of condition While GPCRs have been found to be involved in many different processes and have been the target of much research and drug discovery, unless the specific ligand for each receptor is known, unless the biological activity of the receptor is disclosed or unless the processes and diseases that each receptor is involved in are identified, the method of identifying a compound which modulates a recepto has no "real world" use, and therefore, lacks specific and substantial utility.
Claims 38-46 were rejected because the claims specifically recite that the identified compounds must be capable of treating disease, which treatment is not enabled. Applicant argues that the claims are directed to methods of identification of compounds which modulate I5E. However, the claims as written are directed to identifying compounds which are capable of treating an immune, central nervous system or metabolic disorder, schizophrenia, cognitive disorders multiple sclerosis or depression. In order for the skilled artisan to practice such a method it would be necessary for the artisan to determine the role of I5E in all of these disorders, then design assays for compound identification wherein the compound could modulate the I5E polypeptide such that each and every one of these maladies would be treated. Thus, it would require undue experimentation for one of ordinary skill in the art to practice the claimed invention.

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